

CANDIDATES FOR PREP

- At **substantial risk of HIV acquisition** and 1 of the following:
 - Sexually-active adult **MSM** (men who have sex with men) – **IA**
 - Sexually-active adult **heterosexual men and women** – **IA**
 - Adult persons who inject drugs (**PWID**) – **IA**
- Uninfected partner in HIV-discordant couples during conception and pregnancy – **IIB**
- Insufficient data in adolescents – **IIIB**

SUBSTANTIAL RISK OF HIV ACQUISITION

- HIV-positive sexual partner
- Recent bacterial STI/sexually transmitted infection (syphilis, gonorrhea, chlamydia)
- High number of sex partners
- History of inconsistent or no condom use
- Commercial sex work
- PWID who have HIV-positive injecting partner(s)
- PWID who are sharing injecting equipment



TABLE. CDC Criteria for PrEP Use⁶

TARGET POPULATION	MEN WHO HAVE SEX WITH MEN	HETEROSEXUAL MEN AND WOMEN	PEOPLE WHO INJECT DRUGS
Substantial risk factors for acquiring HIV infection (if at least 1 is present, PrEP should be considered)	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STI Inconsistent condom use Commercial sex work 	<ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STI Inconsistent condom use Commercial sex work Residence in high-prevalence area or sexual network 	<ul style="list-style-type: none"> HIV-positive injection partner Sharing of injection equipment Recent drug treatment (but currently injecting)
Clinical eligibility	<ul style="list-style-type: none"> Documented negative HIV test before PrEP prescription No signs/symptoms of acute HIV infection Normal renal function 		

CDC indicates US Centers for Disease Control and Prevention; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection. Adapted from CDC's Preexposure Prophylaxis for the Prevention of HIV Infection in the United State—2017 Update.⁶

Identifying eligible patients

- **CDC guidance document¹**
 - Ask questions about sexual and injecting risk taking
 - Clues: recent STIs or pregnancy in the past 6/12

BOX A1: RISK BEHAVIOR ASSESSMENT FOR MSM³⁶

In the past 6 months:

- Have you had sex with men, women, or both?
- *(if men or both sexes)* How many men have you had sex with?
- How many times did you have receptive anal sex (you were the bottom) with a man who was not wearing a condom?
- How many of your male sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive male partners, how many times did you have insertive anal sex (you were the top) without you wearing a condom?
- Have you used methamphetamines (such as crystal or speed)?

May be difficult for patients to provide questions?

- Risk of disappointing doctors/ losing
- Risk of criminal liability in some jurisd

BOX A2: RISK BEHAVIOR ASSESSMENT FOR HETEROSEXUAL MEN AND WOMEN

In the past 6 months:

- Have you had sex with men, women, or both?
- *(if opposite sex or both sexes)* How many men/women have you had sex with?
- How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
- How many of your sex partners were HIV-positive?
- *(if any positive)* With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?

1. CDC PrEP for prevention of HIV in the United States, 2014 Clinical Practice Guideline

Box B1: RECOMMENDED INDICATIONS FOR PREP USE BY MSM²

- Adult man
- Without acute or established HIV infection
- Any male sex partners in past 6 months (if also has sex with women, see Box B2)
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following

- Any anal sex without condoms (receptive or insertive) in past 6 months
- A bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in past 6 months

Box B2: RECOMMENDED INDICATIONS FOR PREP USE BY HETEROSEXUALLY ACTIVE MEN AND WOMEN

- Adult person
- Without acute or established HIV infection
- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual) [also evaluate indications for PrEP use by Box B1 criteria]
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

Box B3: RECOMMENDED INDICATIONS FOR PREP USE BY INJECTION DRUG USERS

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months
- Risk of sexual acquisition (also evaluate by criteria in Box B1 or B2)

ASSESSMENT OF RISKS

- HIV testing negative and no signs of acute HIV
- Renal function
 - eGFR > 60
- Hepatitis B status negative and vaccinated
- Hepatitis C status (esp PWID and MSM)
- Sexually transmitted infections (syphilis and gonorrhea, chlamydia if MSM)
- Pregnancy

ACUTE HIV INFECTION

- Within 1-2 months
- Flu-like illness
 - Fever
 - Rash
 - Headache
 - Lymphadenopathy
 - Diarrhea
 - Fatigue
 - Myalgias
 - Night sweats



Are there signs or symptoms of acute HIV-1 infection, OR is recent exposure (<1 month) to HIV suspected?

NO

YES

DO NOT initiate TRUVADA for PrEP. Wait at least 1 month unless negative HIV-1 status is reconfirmed.

OR

Confirm acute HIV-1 has not been contracted using a highly sensitive, FDA-approved test. If appropriate, consider prescribing TRUVADA for PrEP.

Confirm negative HIV-1 status through testing. If appropriate, consider prescribing TRUVADA for PrEP.

Re-confirm negative HIV-1 status at least every 3 months.

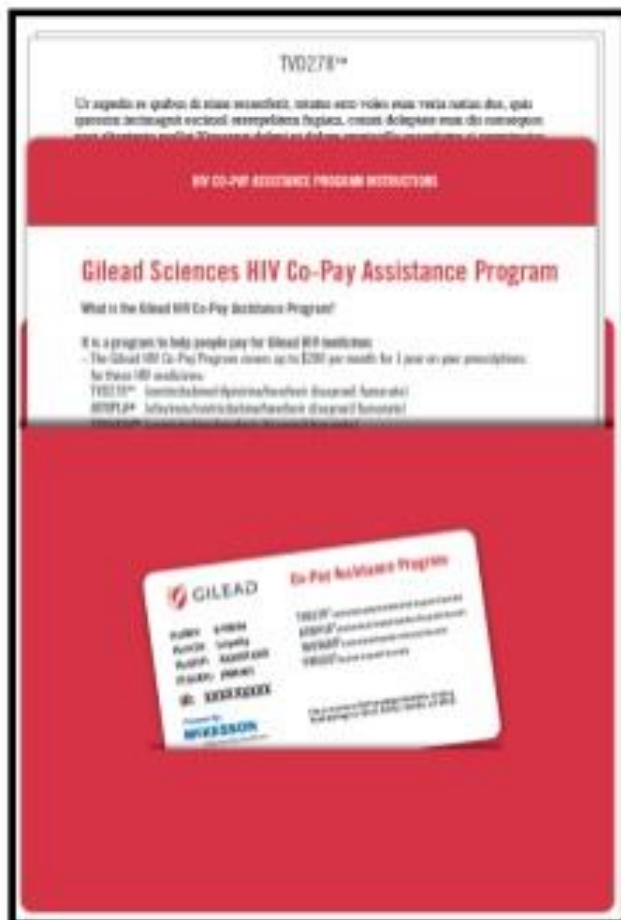
TIME TO ACHIEVING PROTECTION

- Time from initiation of PrEP to maximal protection against HIV is unknown
- Pharmacokinetics of TDF and FTC vary by tissue
- Preliminary data to achieve steady state and maximum intracellular concentrations of tenofovir diphosphate
 - Blood: ~20 days
 - Rectal tissue: ~7 days
 - Cervicovaginal tissues: ~20 days
 - Penile tissues: no data

PRESCRIPTION

- Tenofovir disoproxil fumarate-emtricitabine (TDF-FTC)/Truvada
- Tenofovir alafenamide-emtricitabine (TAF-FTC)/Descovy
 - Indicated for MSM or transgender women only (excludes receptive vaginal sex)
- Once daily
- No food requirements
- Dispense 90-day supply
- Renew only after HIV testing is negative

Co-pay card program



Covers all Gilead HIV Products: Stribild, Complera, Atripla, Truvada, Viread, Emtriva

- Assists patients with commercial insurance who reside in the US, or US Territories
- Not valid for Rx that are eligible to be reimbursed by any federal or state funded healthcare benefit program
- Co-pay benefit provides assistance for co-pays above **\$0**
- Monthly benefit provided for 12 mos after activation of card
 - \$400/month for all STRs (Stribild, Complera, Atripla)
 - **\$300/month for** (Truvada, Viread, Emtriva)
- No maximum lifetime benefit but pts need to recertify after 12 months

Medication assistance form

GILEAD **Truvada® for Pre-Exposure Prophylaxis (PrEP) Medication Assistance Program** Page 1 of 2

Application to be used for TRUVADA for PrEP only
 Fax 1-855-330-5478 to begin enrollment

1 Applicant Information

Applicant Name: _____ Applicant Language: English Spanish Other

Address: _____ State: _____ Zip: _____ Phone # (____) _____

City: _____ Date of Birth: _____ / _____ / _____ Gender: M F Other Yes No

Social Security #: _____ Relationship: _____ Home Number: _____

Primary Contact: _____

Applicant Financial Information

Current Annual Household Income: \$ _____ Number in Household (include self): 1 2 3 4 5 6

Please include correct documentation for all sources of income (eg. tax returns, W-2, and 1099 stubs, etc.)

Applicant is insured (Please check all applicable insurance information below. Attach copy (front and back) of applicant insurance card)

Applicant is uninsured (Do not check this box unless you are uninsured through any public or private plan) Complete "Additional Insurance Information" below.

Primary Paper Name: _____ Paper Phone Number: _____

Plan Name: _____ Policy #: _____ Group #: _____

Subscriber Name: _____

Check box if applicant has secondary insurance coverage and has insurance needs, if available.

Additional Insurance Information

	Yes	No
Has the applicant applied for Medicaid Part (D)?	<input type="checkbox"/>	<input type="checkbox"/>
		If Yes, date of application: _____
		If No, provide reason: _____
Has the applicant applied for Medicare?	<input type="checkbox"/>	<input type="checkbox"/>
		If Yes, date of application: _____

Read entire application for full details. Application will be processed in the order of receipt. All information must be provided to be eligible for assistance. Program is subject to change without notice. © 2014 Gilead Sciences, Inc. All rights reserved.



MONITORING

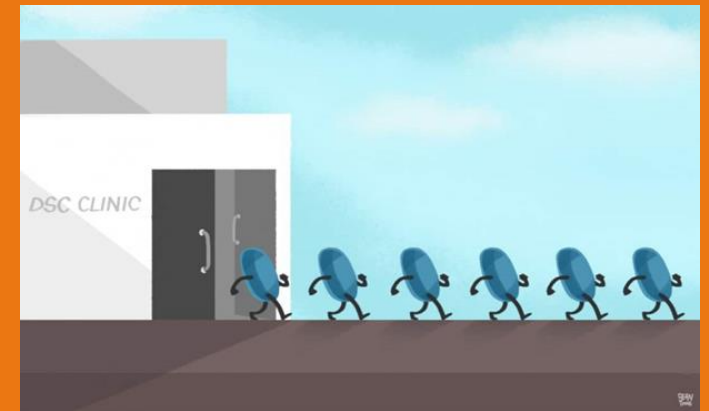
- Follow up appt in 1 month and q 3 months
- Labs q 3 months
 - HIV testing
 - Serum creatinine (CMP)
 - Every 6 months
 - Every 3 months if renal risks
 - HCG test
 - STI testing (GC/CL, RPR)
- Re-assessment q 12 months for need for PrEP

Recommended Laboratory Testing and Frequency for Patients Taking PrEP				
Laboratory test	Baseline	At least every 3 months	At least every 6 months	Notes
HIV screening assay	✓	✓		Consider need for HIV RNA PCR
HBV (panel#) and HCV antibody	✓			Offer HBV vaccination if not immune
Serum creatinine	✓		✓	^CrCl decrease may require stopping PrEP
STI testing	✓	✓	✓	Include oral/rectal screen for MSM if risk
Pregnancy test for women*	✓	✓		Safety of PrEP in pregnancy not known

Abbreviations: eCrCl = estimated creatinine clearance; STI = sexually transmitted infections
 #Includes HBsAg, anti-HBc, and anti-HBs
 ^Do not start tenofovir DF-emtricitabine if CrCl <60 mL/min; do not start tenofovir alafenamide-emtricitabine if CrCl <30 mL/min
 *For women who may become pregnant

COUNSELING

- Medication dosage and schedule
- Potential side effects
- Adherence and efficacy
 - Anal: minimum 4 doses per week for efficacy
 - Vaginal: 6-7 doses per week for efficacy
- Reduction of barriers to adherence
- Education on symptoms of acute HIV
- Risk reduction behaviors (condoms, other STIs, sharing needles)



PERSONS WITH NEW HIV INFECTION

- Confirmatory HIV testing
- CD4, HIV viral load, genotypic HIV resistance
- Convert PrEP to an HIV regimen without awaiting lab results
- Refer to HIV Specialist
- Counseling for their HIV status and risk management
- Notify local health dept for confidential partner notification and testing